Purdue U.S. Board Meeting
October 29th & 30th, 2013

Notes & Actions

1.0 John Stewart's Presentation - In response to the FDA's approval of Zohydro, which is not an abuse-deterrent formulation, there were questions and concerns as to the implications of this decision for the company's strategy of developing a line of abuse deterrent opioid products.

1.1 What can we do to achieve a better understanding of the FDA and the evolution of their thinking/policy regarding encouraging development of abuse-deterrent opioids? Is it possible to make direct contact with influential/informed individuals at the FDA on this issue?

Action: Todd Baumgartner/Burt Rosen – report/action plan by December 20th

1.2 Has there been any sign of Congressional interest/concern over the Zogenix approval decision? If so, can this/these individuals be helpful as we pursue the development and implementation of laws, regulations and policies that support the development and use of abuse-deterrent opioid formulations?

Action Burt Rosen/Alan Must/Raul Damas – report/action plan by December 13th

1.3 It would be very helpful to see data on the nature and extent of abuse of opioid formulations other than OxyContin. For example, what is the extent of abuse of IR oxycodone formulations as compared to OxyContin? The FDA has been stating that OxyContin and other ER/LA formulations are "the problem", but this seems inconsistent with what has been noted about the shift by abusers to Roxicodone 30mg tablets and other forms of IR oxycodone.

Action: Paul Coplan/David Haddox – report by December 20th

1.4 In regard to the ongoing decline in the number of OxyContin prescriptions and the average dose per prescription, what do we know about effects at the patient level? Are patients being switched from high-dose OxyContin to some other product, or are higher doses of other opioids being prescribed in preference to high doses of OxyContin?

Action: David Rosen/David Haddox – report by January 31, 2014

1.5 Butrans – Concern was expressed over the low prescription growth rate. Can we explore promotion pertaining to specific populations (e.g. the elderly) for whom the product seems to be particularly important, and/or should we increase or re-allocate S&P resources? Also, if Butrans sales are expected to peak at $350MM, what percentage of that business will be from Med D Coverage and what percentage will be from Commercial Coverage (Judy Lewent referred to this as the "patient map")? What evidence-based studies do we have to build coverage in Med D Plans?

Action: Gary Lewandowski/Tim Richards/Kerri Pierez – report on specific populations and Med D Plan coverage enhancement by December 20th. S&P resource allocation is a budget-related

and the responsibility of JHS, RJG and Gary Pawlowski.

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1.6 With respect to the entire analgesic line, what is the positioning for each of the products and how are we planning on simultaneously promoting all four (Butrans, OxyContin, Targiniq ER and HydroContin). In association with this question, it was suggested that it may be helpful to understand the prescribing "rationale" for current opioid analgesics (i.e. which analgesic products are prescribed for specific clinical indications – and why?).

Action: John Stewart/Russ Gasdia/Gary Stiles – by December 20th

2.0 Marketing and Sales Presentations

2.1 The Board asked for reports of analyses/market research on the projected impact of the following on the overall opioid analgesic market and our analgesic products – both existing and soon to be launched.

i. The change in scheduling for acetaminophen/hydrocodone combination products
ii. The Affordable Care Act?

Action: Tim Richards/Todd Killian/David Rosen – report by December 13th

2.2 What is our thinking as to the extent that payers will support premium pricing of AD formulations over their non-AD counterparts, currently and in the future?

Action: Tim Richards/Todd Killian/Rami Ben-Joseph – report by December 13th

2.3 In regard to the E2E Project, the following comments/questions were raised:

i. In terms of incentives, the salesforce (and indeed the entire organization) should be driven to be of high value to patients and physicians (and the healthcare system), and not simply to increase prescriptions for Purdue products.
ii. At the level of the individual physician, it is important to minimize disruption of existing, successful relationships between the physicians and sales representatives.
iii. Returning to abuse-deterrent products, it was noted that the epidemiological data is very interesting/compelling – and there is likely a way to have this more broadly understood via actions such as grand rounds, medical education events and the medical/therapeutic groups within payer organizations.

Actions: Russ Gasdia/Tim Richards/Paul Coplan/Lisa Miller – no specific report, execution as part of the E2E implementation and already established plans for 2014

2.4 Managed Care Review

i. With respect to Butrans, Targiniq ER and HydroContin, what do we have (and are preparing to have) in terms of data – so that the MCO's will want to list these products on their formularies?

Actions: Tim Richards/Todd Killian/Rami Ben-Joseph – report by December 20th

ii. For Targiniq ER, what are we likely to be able to communicate about the naloxone component – and what knowledge do we have with respect to physician's thoughts on naloxone in the formulation? For which audiences will we be able to supply the results of the clinical studies performed in the EU or Canada?

Action: Russ Gasdia/Bill Mallin/Gary Stiles – a sub-component of the E2E project. Report date TBD.

3.0 R&D Presentation

3.1 While we have much solid epidemiology data on the impact of AD OxyContin, it does not seem to matter much to patients, prescribers, and Managed Care. What compelling economic (or other) arguments can be used to help reverse the apparent ongoing preference for lower cost, non-AD opioids?

Action: Gary Stiles/Rami Ben-Joseph/Todd Killian – combine with report on item 2.4 i

3.2 Please send the topline results from the HYD Phase 3 Clinical Trial as soon as available.

Action: Gary Stiles – when available – likely the week of December 2nd

3.3 How can electronic health records be used to help with tracking (and reducing) abuse of prescription opioids.

Action: Paul Coplan/David Haddox – Follow-up via RADEX/R&D OPS

3.4 With HYD tablets all being the same size, MDAS expressed concern over the colors chosen for each strength and the lack of consistent color differentiation across our opioid product lines. We should determine if this is truly problematic in the marketplace.

Action: Todd Baumgartner – Report by January 31, 2014

3.5 Should we develop an AD IR hydrocodone formulation?

Action: John Stewart/Business Development Committee – decision as part of long-term budgeting process

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3.6 Should we re-examine the OIC/OIBD focus (of promotion) for Targiniq ER, so as not have the product positioned too narrowly?

Action: John Stewart/Gary Stiles/Russ Gasdia – as part of the response to item 1.6

3.7 Cecil Pickett commented that we should ensure that adequate pharmacovigilance resources are retained in any cost-reduction efforts.

Action: John Stewart - ongoing

4.0 Business Development

4.1 [redacted] Cecil Pickett asked why we are pursuing this particular opportunity (i.e. how did we come to select t[redacted]market) – to which Jim Dolan replied that the market has been growing substantially over the past several years and that there is not currently an [redacted]formulation on the US market – so from that perspective it is a good opportunity to evaluate. Such a move would also be consistent with the goal of expanding the company's therapeutic areas other than pain.

Additional questions that were asked included:

i. Are the major companies already in this market (e.g. Abbvie, Lilly) also pursuing[redacted] and if not, what do we know about their rationale?

ii. It was noted that there is an[redacted]roduct on the market in Canada and Europe, but that it is not commercially successful. What do we know about the reasons for its lack of success, and is this strong evidence that the[redacted]s not as attractive as our market research suggests?

The proposed non-binding offer should be sent to the Board's Business Development Committee for review, recognizing that this would likely result in Purdue not being able to meet the "deadline" for bids of November 11th – which was set/communicated by J.P. Morgan.

Action: Jim Dolan

Post Meeting Note: on[redacted]a study reporting on an apparent relationship between[redacted]was published in JAMA. Until this study and its implications are better understood, Purdue will not submit a non-binding offer to the Board Committee or J. P. Morgan.

4.2 Mortimer Sackler asked about[redacted]and their AD technology, to which John Stewart replied that we are well aware of their activities – and visited them several years back. For a variety of reasons, Purdue decided to pursue AD technologies other than[redacted]

Action: John Stewart to confirm with Rich Mannion Purdue's dealings with[redacted]

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5.0 Corporate Affairs and Communications

5.1 It was recommended that the department's objective statement be broadened/revised in a way to include reference to patients, physician and the overall healthcare/wellness status of the population.

Action: Raul Damas – already complete

5.2 In regards to the CDC data on abuse of prescription opioids, it was noted that "old" data continues to be presented/referenced – and that the company should do what it can to have the CDC report more recent data – and simultaneously correct the errors in the reporting of the older data (e.g. reporting hydromorphone abuse under the category of ER opioids – at a time when no ER hydromorphone product was on the market). At the same time, the company's communications efforts should seek to clarify inaccuracies or misconceptions in the existing CDC (or other) abuse related data.

Action: Raul Damas/David Haddox/Paul Coplan – Report and action plan by January 31, 2014

5.3 Recognizing that abuse of prescription opioids is a serious problem, and that AD formulations are only part of the solution, Ralph Snyderman suggested that the External Affairs and Managed Care Groups consider partnering with states and MCO's respectively on programs that help identify at-risk patients and/or prescribers – perhaps via a pilot program with one or two states/MCOs.

Action: Raul Damas/Alan Must/Tim Richards/Rami Ben-Joseph – part of ongoing AE, MSL, PSL and State Government Relations activities.

6.0 Legal Department

6.1 There was substantial discussion of the approval of Zohydro, and the implication for the future of HydroContin – and indeed the entire extended-release hydrocodone market. Jim Dolan, Ed Mahony, John Stewart and Phil Strassburger were asked to develop models/strategies for Purdue to participate in the marketing and/or future development of Zohydro – and to discuss same with The Board's Business Development Committee

Action: As noted above

Post Meeting Note: the group met with the Board's Business Development Committee (and several other Board Members), and there was agreement that there does not appear to be a deal structure that would be acceptable to both Purdue and Zogenix. As such, it was decided that the recommendation to The Board would be to not pursue any deal with Zogenix. This was subsequently accepted by The Board.

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